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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,141	07/08/2004	Toru Nishibayashi	040243	1413

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EXAMINER

ALI, SHUMAYA B

ART UNIT PAPER NUMBER

3743

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/500,141

Applicant(s)

NISHIBAYASHI ET AL.

Examiner

Shumaya B. Ali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: DETAILED ACTION.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I, claim(s) 1-5,10-20, drawn to a powder inhalator.**

**Group II, claim(s) 6-9, drawn to a powder inhalator.**

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: **group II contains a special technical feature, "a protective cap" which is missing from group I.**

3. During a telephone conversation with **Jamy Armstrong** on **10/13/2005** a provisional election was made **without** traverse to prosecute the invention of **group I, claims 1-5,10-20.**

Affirmation of this election must be made by applicant in replying to this Office action. Claims **6-9** withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As to claim 1, “circular manner” is vague. Recitation from the original disclosure seem to render sliding movement between the drug discharge aperture and an inhalation channel. It is not clear how the “circular manner” movement is obtained when the sliding member moves back and forth, hence providing sliding movement.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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**7. Claims 1,2,4,5,10-13 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Leary US Patent No. 6,718,972 B2.**

As to claim 1, O'Leary discloses a powder inhalator in figures 1-16 comprising:

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a housing (18), a supply member (14) for holding a powdered drug for a large number of doses and having a drug discharge aperture (46) at its bottom surface; a drug carrier (42), to which the powdered drug is supplied from the drug discharge aperture of the supply member, and having on its upper surface a measuring recess (102) that has volume equivalent to one dose of the drug; and an operation member (100) disposed so as to move freely back and forth, and operate the drug carrier the drug carrier moving in contact with the bottom surface of the supply member to carry the powdered drug loaded into the measuring recess from the position of the drug discharge aperture to an air inhalation channel (34), wherein the drug carrier is supported pivotable in the housing so that the measuring recess moves in a circular manner (**considered sliding**) by pivoting the drug carrier.

**As to claim 2, O'Leary discloses** wherein the measuring recess is located at a position between the center of the pivotal movement of the drug carrier and the point at which the operation member engages the drug carrier (**see col.5 lines 45-57**).

**As to claim 4, O'Leary discloses Claim 4 (currently amended):** The powder inhalator according to claim 3, wherein conductivity is imparted to the supply member, the drug carrier and the operation member (**supply member and drug carrier and the operation member are taught by O'leary, therefore, the structures are inherently capable of meeting the claimed limitation**).

**As to claim 5, O'Leary discloses** the powder inhalator according to claim 4, wherein the measuring recess is a spherical concave ("**cup**", **see col.5 line 49**) shape and provided with a bottom.

**As to claim 10, O'Leary discloses** the powder inhalator according to claim 2, wherein conductivity is imparted to the supply member, the drug carrier and the operation member **(supply member and drug carrier and the operation member are taught by O'leary, therefore, the structures are inherently capable of meeting the claimed limitation).**

**As to claim 11, O'Leary discloses** The powder inhalator according to claim 10, wherein the measuring recess is a spherical concave shape ("**cup**", **see col.5 line 49**) and provided with a bottom.

**As to claim 12, O'Leary discloses** The powder inhalator according to claim 2, wherein the measuring recess is a spherical concave shape ("**cup**", **see col.5 line 49**) and provided with a bottom.

**As to claim 13, O'Leary discloses** The powder inhalator according to claim 3, wherein the measuring recess is a spherical concave shape ("**cup**", **see col.5 line 49**) and provided with a bottom.

**As to claim 20, O'Leary discloses** the powder inhalator according to claim 1, wherein the measuring recess is a spherical concave shape ("**cup**", **see col.5 line 49**) and provided with a bottom.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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**8. Claims 3,14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary US Patent No. 6,718,972 B2.**



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**As to claim 3, O'Leary discloses** wherein the operation member is a pushbutton (108) and the operation member is pressed to move the measuring recess into the air inhalation channel (col.5 lines 45-57).

**As to claim 14, O'Leary discloses** the powder inhalator according to claim 1, wherein the operation member is a pushbutton (108) and the operation member is pressed to move the measuring recess into the air inhalation camel (col.5 lines 45-57).

**As to claim 15, O'Leary discloses** the powder inhalator according to claim 14, wherein conductivity is imparted to the supply member, the drug carrier and the operation member. (Supply member and drug carrier and the operation member are taught by O'leary, therefore, the structures are inherently capable of meeting the claimed limitation).

**As to claim 16, O'Leary discloses** the powder inhalator according to claim 15, wherein the measuring recess is a spherical concave shape ("cup", see col.5 line 49) and provided with a bottom.

**As to claim 17, O'Leary discloses** the powder inhalator according to claim 14, wherein the measuring recess is a spherical concave shape ("cup", see col.5 line 49) and provided with a bottom.

**As to claim 18, O'Leary discloses** the powder inhalator according to claim 1, wherein conductivity is imparted to the supply member, the drug carrier and the operation member. (Supply member and drug carrier and the operation member are taught by O'leary; therefore, the structures are inherently capable of meeting the claimed limitation).


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As to claim 19, O'Leary discloses the powder inhalator according to claim 18, wherein the measuring recess is a spherical concave shape ("cup", see col.5 line 49) and provided with a bottom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shumaya B Ali  
Examiner  
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